IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF WISCONSIN

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NOVOZYMES A/S and
NOVOZYMES NORTH AMERICA, INC.,

OPINION and ORDER

Plaintiffs,

10-cv-251-bbc

v.

DANISCO A/S,
GENECOR INTERNATIONAL WISCONSIN, INC.,
DANISCO US INC. and DANISCO USA INC.,

Defendants.

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Plaintiffs Novozymes A/S and Novozymes North America, Inc. and defendants Danisco A/S, Genecor International Wisconsin, Inc., Danisco US Inc. and Danisco USA Inc. make and sell enzymes called alpha-amylases used in making ethanol and other products. In this case for patent infringement, defendants have filed an early motion for summary judgment on the question whether plaintiff's U.S. Patent No. 7,713,723 is invalid because it does not have an adequate written description as required by 35 U.S.C. § 112. In an order dated September 24, 2010, I denied plaintiffs' motion for a preliminary injunction in part because I concluded that defendants had raised a substantial question about the adequacy

of the written description. Defendants' motion for summary judgment is ready for decision.

Although I still have doubts that the specification in the '723 patent provides an adequate written description for the claims, I conclude that defendants have not met their burden to prove by clear and convincing evidence that the '723 patent is invalid as a matter of law. Accordingly, I am denying defendants' motion for summary judgment.

The invention at issue in this case is a relatively straightforward one. In a nutshell, it rests on the concept that certain alpha-amylases will continue breaking down molecules under high temperatures for a longer period of time if one replaces the amino acid serine at position 239 with one of 19 other possible amino acids. (The claims do not identify which amino acid should be used. Although defendants argued at the preliminary injunction hearing that the vagueness of the claims created a problem related to enablement, they do not reassert that argument in their motion for summary judgment.) According to the patent, the invention may be useful in ethanol production, as well as a variety of other contexts, such as laundry detergent and sweetener production. '723 pat, col. 1, lns. 34-36.

The '723 patent has 17 claims in total, but claim 1 is representative for the purpose of defendants' motion:

An isolated variant of a parent alpha-amylase, wherein:

(a) the variant has at least 90% sequence identity to SEQ ID NO: 6,

(b) the variant comprises a substitution of serine at position 239 relative to

> the parent alpha-amylase, using the amino acid sequence of SEQ ID NO: 8 for determining position numbering, and
>
> (c) the variant has increased thermostability relative to the parent alpha-amylase, wherein thermostability is determined at pH 4.5, 90° C. and 5 ppm calcium and has alpha-amylase activity.

The question presented by defendants' motion for summary judgment is whether the '723 patent's specification, which was filed in 2000, provides an adequate written description for the claims, which were not filed until 2009. In particular, defendants argue that the specification does not disclose "a substitution of serine at position 239" and "increased thermostability relative to the parent alpha-amylase," limitations that appear in all of the claims in the '723 patent.[1]

The written description requirement comes from the first paragraph of 35 U.S.C. § 112 ("The specification shall contain a written description of the invention. . ."). The statute does not elaborate on the requirement, leaving that job to the courts. The Court of Appeals for the Federal Circuit has articulated the standard in various ways. In Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1566 (Fed. Cir. 1991), the court framed the question as "whether the [specification] conveyed with reasonable clarity to those of ordinary skill that [the inventor] had in fact invented the [invention] recited in those claims." In Enzo Biochem,

[1] Although the claim language suggests that serine is the substitute, the parties agree that serine is the original amino acid at position 239 and another amino acid is the substitute.

Inc. v. Gen-Probe Inc., 323 F.3d 956, 968 (Fed. Cir. 2002), the court stated that "[t]he disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described." And in Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323 (Fed. Cir. 2000), it stated that "one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims."

Perhaps the most common statement from the Court of Appeals for the Federal Circuit regarding the meaning of the requirement is that a written description is adequate if it shows to a person of ordinary skill in the art that the inventor "had possession" of the claimed invention as of the filing date. Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010); LizardTech, Inc. v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005); Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319 (Fed. Cir. 2003); Union Oil Co. of California v. Atlantic Richfield Co., 208 F.3d 989, 1001 (Fed. Cir. 2000). In Ariad, 598 F.3d at 1351, the court attempted to explain what it meant by "possession":

> The term "possession," however, has never been very enlightening. It implies that as long as one can produce records documenting a written description of a claimed invention, one can show possession. But the hallmark of written description is disclosure. Thus, "possession as shown in the disclosure" is a more complete formulation. Yet whatever the specific articulation, the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.

The purpose of the requirement is to prevent patent owners from using the amendment process to "update" their invention or take credit for an invention that was not disclosed. Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1255 (Fed. Cir. 2004) ("The written description requirement prevents applicants from using the amendment process to update their disclosures (claims or specifications) during their pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of invention."); Vas-Cath, 935 F.2d at 1561 (quoting Rengo Co. v. Molins Machine Co., 657 F.2d 535, 551 (3d Cir. 1981)) ("'Adequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.'").

The court of appeals has held that the adequacy of the written description is a question of fact. Laryngeal Mask Co. Ltd. v. Ambu, 618 F.3d 1367, 1373 (Fed. Cir. 2010). Like any other defense of invalidity, the inadequacy of the written description must be proven by defendants with clear and convincing evidence. Id. 1373-74.

In almost every case in which the Court of Appeals for the Federal Circuit has found a written description lacking, the problem has been that a particular limitation is simply not present in the specification. E.g., University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 927 (Fed. Cir. 2004) ("It is undisputed that the '850 patent does not disclose any

compounds that can be used in its claimed methods."); Purdue Pharma, 230 F.3d 1320, 1327 ("What the '360 patentees have done is to pick a characteristic possessed by two of their formulations, a characteristic that is not discussed even in passing in the disclosure, and then make it the basis of claims that cover not just those two formulations, but any formulation that has that characteristic."); In re Ruschig, 379 F.2d 990, 993 (1967)("[N]owhere in the specification is the particular selection indicated."). This is a potential problem for defendants because, in this case, there is no question that each of the limitations is discussed in the specification.

With respect to "a substitution of serine at position 239," the specification includes the following discussion:

> variant[s] of a parent Termamyl-like alpha-amylase, comprising an alteration at one or more positions (using SEQ ID NO:8 for the amino acid numbering) selected from the group of:
>
> 49, 60, 104, 132, 161, 170, 176, 179, 180, 181, 183, 200, 203, 204, 207, 212, 237, 239, 250, 280, 298, 318, 374, 385, 393, 402, 406, 427, 430, 440, 444, 447, 482,
>
> wherein
>
> (a) the alteration(s) are independently
>
> (i) an insertion of an amino acid downstream of the amino acid which occupies the position;
>
> (ii) a deletion of the amino acid which occupies the position, or

> (iii) a substitution of the amino acid which occupies the position with a different amino acid,
>
> (b) the variant has alpha-amylase activity and
>
> (c) each position corresponds to a position of the amino acid sequence of the parent Termamyl-like alpha-amylase having the amino acid sequence shown in SEQ ID NO:8.

'723 patent, col. 7, lns. 36-57. In this passage, position 239 is listed as one of 33 possible positions and a substitution is listed one type of "alteration."

With respect to the limitation "increased thermostability relative to the parent alpha-amylase," the patent does not use those exact words. However, there are several references to an "alteration" in stability at high temperatures. E.g.,'723 patent, col. 1, lns. 28-36. One passage discusses "achieving altered stability, in particular improved stability (i.e., higher or lower), at especially high temperatures." '723 pat., col. 16, lns. 39-48.

The problem with the written description as defendants see it is that it does not point toward the claims, but buries them within a sea of possibilities. In particular, defendants say that the specification identifies a staggering 8.589×10^{42} possibilities for experimentation, without highlighting the variants now claimed. In other words, the specification does not connect the dots between position 239, a substitution at that position and increased thermostability.

Plaintiffs say that there is nothing wrong with including multiple possibilities in the

specification. They rely on Application of Driscoll, 562 F.2d 1245(CCPA 1977), in which the court considered whether it was permissible to claim an invention involving "a class of chemical compounds in terms of a structural formula wherein the substituents thereof are defined as 'a member selected from the group consisting of A, B, C, D * * *.'" The court referred to these classes as Markush groups, after the name of a case in which they were first discussed. Id. (citing Ex parte Markush, 1925 C.D. 126, 340 O.G. 839). The court concluded that the groups were permissible because "[i]t is generally understood that in thus describing a class of compounds an applicant is, in effect, asserting that the members of the Markush group do not fall within any recognized generic class, but are alternatively usable for the purposes of the invention, and therefore, regardless of which of the alternatives is substituted on the basic structure, the compound as a whole will exhibit the disclosed utility."

Plaintiffs are correct that, in Driscoll, the court of appeals approved the use of describing multiple possibilities in the specification so long as each is "alternatively usable for the purposes of the invention." Driscoll, 562 F.2d at 1249. Further, in disclosing the 33 different positions, the specification of the '723 patent uses the phrase "selected from a group of" that often signals the introduction of a Markush group. Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1372 (Fed. Cir. 2005) ("Claim drafters often use the term 'group of' to signal a Markush group. A Markush group lists specified alternatives in a

patent claim, typically in the form: a member selected from the group consisting of A, B, and C."). Defendants do not identify any way of distinguishing the 33 different positions in this case from the 14 variable compounds at issue in Driscoll. Plaintiffs' expert has testified without contradiction that a person of ordinary skill in the art would interpret the specification as disclosing 33 positions, *each* of which will lead to beneficial results when modified. Arnold Decl. ¶ 28, dkt. #153.

The situation in this case is not identical to Driscoll because more than just one variable is involved. Not only does the specification identify 33 different positions, it identifies three different potential modifications (a substitution, a deletion or an insertion) and two potential results (higher or lower stability). These additional variables were the primary reason that I concluded in the September 24 order that defendants raised a substantial question about the written description.

In their summary judgment materials, plaintiffs point to additional evidence showing that a person of ordinary skill in the art would understand from the disclosure that plaintiffs possessed the invention that later became the claims of the '723 patent. With respect to the different potential modifications, plaintiffs cite the following passage from the specification:

> when a position suitable for modification is identified herein without any specific modification being suggested, it is to be understood that any amino acid residue may be substituted for the amino acid residue present in the position. Thus, for instance, when a modification of an alanine in position 30 is mentioned, but not specified, it is to be understood that the alanine may be

> deleted or substituted for any other amino acid, i.e., any one of: R,N,D,A, C,Q,E,G,H,I,L,K,M,F,P,S,T,W,Y,V.

'723 pat., col. 2, lns. 22-30. Again, plaintiffs' expert testified without contradiction by defendants that a person of ordinary skill in the art would understand this passage to mean *all* potential substitutions are permissible when one is not specifically identified. Arnold Decl. ¶ 30, dkt. #153. In fact, defendants do not address this passage at all in their summary judgment materials.

With respect to the "increased thermostability" limitation, plaintiffs point to several different passages in the specification. First, they note that the specification makes it clear that the invention is meant to be "suitable for starch conversion, ethanol production, laundry wash, dish wash, hard surface cleaning, textile desizing, and/or sweetener production," '723 pat., col. 1, lns. 28-36, all industrial processes for which it would make no sense to have *decreased* stability at high temperatures. Arnold Decl. ¶ 37, dkt. #153. Defendants do not point to any examples in which lower stability would be considered an improvement. Second, plaintiffs note that the specification directs the reader to the "Materials and Methods" section to determine stability. '723 pat., col. 16, lns. 47-48. That section describes "[i]mproved variants" as those with "higher residual activity." '723 pat., col. 23, lns. 4-5. Defendants do not dispute plaintiffs' proposed finding of fact that "[o]ne of ordinary skill in the art would understand that stability, determined as described in the

'Materials and Methods' section, describes increased thermostability as taught by the assays described in this section." Plts.' PFOF ¶ 153, dkt. #151; Dfts.' Resp. to Plts.' PFOF, ¶ 153, dkt. #165. Finally, plaintiffs point out that each of the examples described in the specification results in increased thermostability rather than decreased thermostability. '723 pat. col. 25, ln. 41; col. 26, ln. 46.

Defendants do not respond to any of these arguments in their reply brief. (In fact, a general difficulty in this case has been the parties' tendency to argue past each other.) Instead, they cite the passage in which in the specification describes "improved" stability as either "higher or lower," '723 pat., col. 16, ln. 42, and they point to tests showing that *lower* thermostability is the result of the one preferred embodiment in the specification that involves a substitution at position 239. Dfts.' Br., dkt. #123, at 6; Dfts.' Reply Br., dkt. #161, at 10. Defendants raise the argument about the test results for the first time in their reply brief, so I cannot consider it. In any event, the conflicting data seems to support a conclusion that a genuine issue of material fact exists rather than demonstrate as a matter of law that the written description is inadequate.

It is not without hesitation that I am denying defendants' motion. Plaintiffs do not contradict defendants' observation that, if plaintiffs' position is accepted, it means that plaintiffs disclosed 8.589×10^{42} possible inventions in their specification. However, to the extent the specification would require undue experimentation before a person of ordinary

skill in the art could discover the claimed invention, that may suggest a lack of enablement rather than a problem with the written description. Genentech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1365 (Fed. Cir. 1997) ("To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.").

Defendants cite one case in which the court of appeals characterized a problem of "too many possibilities" as a problem related to the written description, Fujikawa v. Wattanasin, 93 F.3d 1559, 1571 (Fed Cir. 1996). In that case, the court stated that it may not be enough to include a claimed chemical compound in the specification as part of a "lis[t] [of] one possible choice for one position" because, if "this [were] the case, a 'laundry list disclosure of every possible moiety for every possible position would constitute a written description of every species in the genus. This cannot be because such a disclosure would not 'reasonably lead' those skilled in the art to any particular species." Id.

I conclude that Fujikawa does not require judgment in defendants' favor for two reasons. First, the court did not suggest that it was handing down a flat rule that all specifications including a large number of possible inventions fail to comply with the written description rule. In fact, the court did not distinguish Driscoll or even cite it. Rather, the court said only that listing a moeity somewhere in that specification does not necessarily mean that "there is ipsis verbis support for every species or sub-genus that chooses that

moiety." Fujikawa, 93 F.3d at 1571. The ultimate question is whether the specification would reasonably lead those skilled in the art to the claims. Id. Because plaintiffs have adduced evidence in this case that the specification of the '723 patent does just that, Fujikawa is not controlling.

Second, and perhaps even more important, the procedural posture of Fujikawa was significantly different from this case. The court was not considering whether the defendant was entitled to judgment as a matter of law in a case for infringement. Rather, the court was determining whether the decision of the Board of Patent Appeals was "clearly erroneous" in finding the written description to be inadequate. This standard of review may have been dispositive, as the court noted the merit of the opposing view. Id. at 1571 ("While Fujikawa's arguments are not without merit, we cannot say, on this record, that the Board's decision was clearly erroneous."). Thus, Fujikawa may be best read as supporting a conclusion that a reasonable jury could conclude that the written description is adequate under facts in similar cases.

ORDER

IT IS ORDERED that the motion for summary judgment filed by defendants Danisco A/S, Genecor International Wisconsin, Inc., Danisco US Inc. and Danisco USA Inc., dkt.

#121, is DENIED.

Entered this 4th day of February, 2011.

BY THE COURT:
/s/
BARBARA B. CRABB
District Judge